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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,104	11/25/2003	Daniel P. Becker	01414/1/US (6794-000080/U)	6396
28880	7590	03/23/2006	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			PERLINGER, SARAH E	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 03/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/722,104	<b>Applicant(s)</b> BECKER ET AL.	
	<b>Examiner</b> Sarah E. Perlinger	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Claims 1-83 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1-8, 10-55, 62, 69, 76-83 drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> together with the carbon to which they are both bonded, form a pyranyl ring and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound, classified in class 549, subclass 13. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup>, X, Y, Z will also be required. Further restriction may be required.
  - II. Claims 1-7, 9-16, 18, 20, 22, 24, 26-27, 29-33, 35, 37-42, 44, 46-54, 62, 69, 76-81, 83 drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> together with the carbon to which they are both bonded, form a piperidine ring and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound classified in class 546, subclass 184. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup>, X, Y, Z will also be required. Further restriction may be required.
  - III. Claim 78 and claims 1-7, 10-16, 18, 20, 22, 24, 26-27, 29-31, 33, 35, 37-42, 44, 46-54, 62, 69, 76, 77, 79-81, 83 as they read on claim 78 but not groups I or II, drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> form a ring with the carbon to which they are both bonded and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound classified in various classes and subclasses depending on species election. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup> will also be required. Further restriction may be required.
  - IV. Claims 1-6, 37, 50-51, 62, 69, 76-77 drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> form a 4-member oxygen-containing ring with the carbon to which they are both bonded and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound classified in class 549, subclass 88. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup> will also be required. Further restriction may be required.
  - V. Claims 1-6, 37, 50-51, 62, 69, 76-77 drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> form a 5-member oxygen-containing ring with the carbon to which they are both bonded and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound classified in class 549, subclass 29. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup> will also be required. Further restriction may be required.

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- VI. Claims 1-6, 37, 50-51, 62, 69, 76-77 drawn to a compound or salt wherein A<sup>2</sup> and A<sup>3</sup> form a bicyclic ring system with the carbon to which they are both bonded and a pharmaceutical composition wherein the composition comprises a therapeutically-effective amount of said compound classified in various class and subclasses, depending on a species election. If this group is elected, an election of species with regard to A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, E<sup>1</sup>, E<sup>2</sup>, E<sup>3</sup>, E<sup>4</sup>, R<sup>x</sup> will also be required. Further restriction may be required.
- VII. Claims 56-61, 63-68, 70-75, drawn to a method for treating a condition associated with pathologically excessive matrix metalloprotease, TNF- $\alpha$  convertase or aggrecanase activity in a mammal comprising administering a compound of claim 1, 37, or 50, classified in various classes and subclasses depending on the election of a compound and condition to be treated. If this group is elected, election of a single disclosed condition and compound will be required.

The inventions are distinct, each from the other because of the following reasons:

The compounds of groups I-VI differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render another group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The search for each diverse core structure as delineated is not coextensive with each other and will constitute an enormous burden.

Inventions I-VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for treating a condition associated with pathologically excessive matrix metalloprotease, TNF- $\alpha$  convertase or aggrecanase activity in a mammal can be practiced with another materially different product than those of groups I-III. For example, Rofecoxib has been used to treat alzheimers and certain types of cancer (see Hashimoto et al., *J. Med. Chem.*, 2002, 45, 1511).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

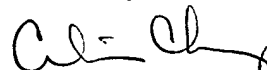
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SP  
03/16/2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625